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Mr. Nicholas Godici
Acting Undersecretary of Commerce and
Acting Director of the United States Patent and Trademark Office
Box 4
Patent and Trademark Office
Washington, DC 20231

ATTN: Mr. Jon Santamauro

Dear Mr. Godici,

I am writing on behalf of the Biotechnology Industry Organization (BIO) in response to your invitation for public comments on questions pertaining to global patent law harmonization (66 FR 15409), dated March 19, 2001. BIO is a trade association representing more than 900 companies and entities focused on research, development and commercialization of inventions in the field of biotechnology.

I. Introduction

BIO Members face significant practical problems in obtaining patent rights around the world. Perhaps the biggest problem is the high cost and procedural complexity of repetitious concurrent examination and registration procedure. The high costs also arise from a range of factors such as translations, local issuance fees, national annuity fees and mandatory use of local counsel in each jurisdiction for compliance with substantive prosecution and or registration procedures. Harmonization will have significant value to BIO members if it removes the sources of these unnecessary costs and complications.

Comprehensive harmonization, however, has failed each time it has been attempted. This has resulted in a series of treaties and agreements that provide partial solutions to the problem. In particular:

- The Patent Cooperation Treaty (PCT) harmonized certain application requirements and established a generalized global application procedure;
- The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), under the Agreement Establishing the World Trade Organization (WTO), harmonized certain substantive standards regarding patents and created generalized obligations regarding enforcement of patent rights; and

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- The Patent Law Treaty (PLT), concluded last year, focuses on harmonization of certain formal requirements of patent applications, outside the structure of the PCT.

Each of these instruments falls short in terms of enabling our companies to obtain the full scope of protection that we need for our inventions, and to do so in a cost-effective and timely fashion.

The difficulty of achieving true harmonization is attributable to the well-established but distinct nature of the world's patent systems, along with industries and practices that are grounded on those systems. Even within Europe, under a harmonized set of legal standards, there are procedural distinctions in each country, and localized practices that can differ dramatically. Consequently, it should be recognized that total and complete harmonization is an unrealistic goal, particularly within the next five to seven years.

A more realistic short-term target is a treaty that achieves "true harmonization" of those elements of patent systems that are necessary to create a streamlined global patent granting system. True harmonization means a treaty that imposes identical standards on substantive patentability among all treaty signatories, rather than a treaty that accommodates a range of options.¹ Patent systems based on such a treaty should capture the best elements of the U.S., European and Japanese patent systems. As noted below, in many respects, the "U.S." versions of the various elements of a harmonized patent system are, in the opinion of BIO Members, the "best" option and must be preserved. However, BIO also recognizes that in certain respects, the "best practice" may not be the version found in the United States patent system.

True harmonization will have little practical value if it does not enable BIO Members to obtain patents more readily than is possible under existing world practice. Simply put, under a truly harmonized system, an applicant should, by right, be able to obtain a patent after a first substantive examination in a major examining office (i.e., the USPTO, the EPO or the JPO). The United States should therefore make it a priority to conclude a treaty that delivers true harmonization of those elements of patent systems necessary to implement the single examination model. Moreover, the United States should not move to conclude a treaty until it is clear that the treaty will yield true harmonization in a form compatible with U.S. interests.

The co-existence of a prospective true harmonization treaty with the PCT suggests that a revised PCT become the vehicle for a facilitated global patent granting system. While this could be seen as a "second best" alternative, it will create a system under which common standards for patentability requirements are adopted, and will enable countries to establish systems that grant patents expeditiously based on the results of a first substantive examination by a major office.

¹ The 1991 exercise is a model of an "accommodation" treaty – such a model cannot be used going forward because it will make impossible a uniform patent granting treaty.

II. Issues Raised for Comment by PTO

A. First to File versus First to Invent

Question from the PTO

(1) As to priority of invention, the United States currently adheres to a first-to-invent system. The remainder of the world uses a first-to-file rule in determining the right to a patent. Please comment as to which standard is the "best practice" for a harmonized, global patent system. It is noted that while the current draft of the treaty does not address this issue explicitly, it is likely that it will be raised in future meetings.

BIO Position:

BIO supports a change of the U.S. system whereby conflicts over inventorship of claimed subject matter will be resolved by granting the patent to the party with the earliest effective filing date (i.e., adoption of a first-to-file system).

BIO also supports measures that incorporate sufficient protections against derivation of inventions (i.e., where information concerning the invention is improperly obtained from the inventor and used to support an application filed prior to the filing of an application by the true inventor).

Remarks

The conversion of the United States system to a "first to file" system is, as a practical matter, a prerequisite to any serious effort to harmonize substantive standards of patent law. The United States is the only country that retains a first to invent system, and simply stated, will not be able to convince other countries to adopt this type of system. Moreover, it would be counterproductive to "export" this feature of United States law because of the complexity, delays, uncertainties, and costs associated with determinations of which inventor made the invention first. By taking the lead in offering to jettison this feature of U.S. patent law, the United States will enhance its ability to convince other countries, primarily significant European nations and Japan, to make similar changes in their systems that represent improvements that are of importance to the United States (e.g. a globalized "grace period"). In other words, without taking this leadership provision in proposing a "best global practices" approach to harmonized patentability standards, it will be impossible to negotiate a satisfactory treaty on substantive harmonization of patent standards.

Conversion of the U.S. system to a first-to-file system nonetheless will be controversial, albeit less controversial than it was in the pre-URAA era. The principal source of concern prior to the URAA was the perceived need for the protection of small, independent inventors. With the advent of low entry barrier patent filing (provisional applications), the globalization of "invention date proofs," and the continuing complexity

and technicality of patent interference contests, the interests of “small entities” will be better served with the simplicity, speed, economy, and predictability of a global “first-to-file” rule.

BIO accordingly supports conversion of the U.S. system to a first-to-file system. BIO also encourages adoption of provisions that will protect, on a global basis, the interests of inventors and applicants against derivation of their inventions. Specifically, BIO supports retention of measures in the treaty and regulations that enable the “true inventor” from whom an invention has been improperly derived from negating the otherwise patent-defeating effect of an earlier filing by a party that has derived the invention. Such provisions would remove some of the concerns of the U.S. independent inventor community and build broader support for harmonization.

B. Patentable Subject Matter

Questions from PTO

(2) As to what inventions may be considered patentable subject matter, the United States currently provides a test of whether the invention is within one of the statutory categories of 35 U.S.C. 101 and within the “useful arts” as expressed in the United States Constitution. The “useful arts” test requires that the claimed invention have a practical application providing a “useful, concrete and tangible result,” see State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998). In contrast, the patent laws of some countries require that the invention provide a “technical contribution” in order to be eligible to be patented. The “technical contribution” requirement is generally considered to be more restrictive in determining what inventions may be patented.

(6) United States law currently provides a utility requirement for patentability in 35 U.S.C. 101. Utility of an invention must be specific, substantial and credible. Most other patent systems have a requirement for industrial applicability. Industrial applicability is generally considered to be a narrower standard than utility, as it requires that the invention be usable in any type of industry.

BIO Position:

BIO supports a treaty provision that would mandate the broadest possible eligibility of patentable subject matter. Specifically, BIO believes subject matter eligibility should be extended to plant and animal inventions, as well as other subject matter excluded under Article 27.3 of the TRIPS Agreement. BIO would oppose any treaty that required the United States to exclude subject matter presently eligible to be patented under U.S. law. BIO thus supports the concepts embodied in proposed Article 11 of the old-style treaty.

BIO also supports treaty language that is based on the U.S. standard for “utility” (i.e., that the invention must have a “practical application” in some field of endeavor). BIO would oppose any treaty requirement that an invention have a “technical effect” to be regarded as “useful” and would oppose an interpretation of the “industrial applicability” standard that requires utility in an identified “industrial” application or field. BIO thus opposes the format used in the “old style” treaty regarding industrial application to the extent that it that limits eligibility to defined industries. BIO recommends the following substitute language for Article 11:

An invention shall be deemed to be industrially applicable if, at the time of the filing of the patent application, a practical and specifically defined use for the invention in any field or in any industry is identified by the applicant

Remarks

Imposing a global standard requiring broad patent eligibility for all inventions that are new, useful and nonobvious is a crucially important objective for BIO. The TRIPS Agreement currently falls short in this regard as it provides its members with the authority to exclude certain types of process inventions, as well as plant and animal inventions, per se, regardless of whether those inventions are new and nonobvious.² Recent debates in Geneva have also suggested that WTO Members have the authority to exclude other subject matter related to living organisms due to a perceived lack of consensus as to the meaning of the term “microorganism.”³ BIO is also aware of some efforts to define patent eligibility at the national level in terms of whether subject matter claimed is a “discovery” as opposed to being an “invention.” Such efforts seek to preclude the issuance of patents on inventions, including compositions, derived from natural sources under a theory that such inventions are “products of nature,” regardless of whether the purified composition or isolated compound meets the requirements of being new, nonobvious and useful.

From BIO’s perspective, it is essential that these real or perceived “loopholes” in the system be closed, so that the full range of inventions that are new and nonobvious will be able to obtain patent protection. BIO and its Members would strongly oppose any treaty that would require the United States to exclude from patent eligibility subject matter that may be patented today under U.S. law. In particular, BIO would strongly oppose a treaty formulation that would require the United States to exclude plant or

² Article 27.3(a) permits WTO Members to exclude “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”. Article 27.3(b) permits WTO Members to exclude “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.” If the latter exclusion is invoked, WTO Members must make protection available for plant varieties through a *sui generis* system of protection.

³ For example, some countries have argued that microorganism is limited to bacteria and yeasts, and cannot extend to other subject matter, including transformed human or animal cells.

animal inventions, human or animal cell lines, process inventions related to diagnosis or treatment of humans or animals, or any form of chemical compound (e.g., nucleic acids, proteins).

BIO also notes that addressing the issue of patent eligibility will be, as a practical matter, unavoidable in these negotiations. This is a consequence of the fact that the WIPO exercise is aimed at achieving true harmonization of patent systems, which means that there will have to be uniformity as to eligibility of subject matter and the standards for industrial applicability/utility. As such, it will be necessary for the United States and other countries to reach a consensus on “narrowing” the TRIPS exceptions to patent eligibility in these negotiations.

In light of the fact that all major developed country systems make eligible patents on animal and plant inventions, it would seem to be a natural point of consensus for the developed countries to support extension of eligibility to the subject matter to plants and animals (i.e., to remove the discretion of 27.3(b) to exclude plant and animal inventions). Given that there are differences between the United States and EPC members as to the subject matter of Article 27.3(a) (i.e., methods of therapy and diagnosis practiced on the human body), it is less clear that a consensus can be easily forged as to a provision that would mandate eligibility for such process inventions. Having said this, the simple formulation in the “old style” treaty proposal is preferable, as it conforms best to existing U.S. practice.

The second element of this topic concerns the optimal treaty formulation for the requirement of “utility” or “industrial applicability” of patentable inventions. Again, BIO members benefit most by an inclusive and generous standard for eligibility that tracks the U.S. standard. As such, BIO supports a definition in the treaty that uses the U.S.-style formulation of the utility requirement; namely, a requirement that the invention fall within one of four recognized statutory categories, and that the invention have a “practical utility.”

Treaty language that accurately captures the U.S. standard should be pursued as an important objective for the negotiations. The formulation suggested in the “old style” treaty does not seem susceptible of such a definition, given its structure. As a consequence, a simpler and more direct formulation may be a better starting point for negotiations. For this reason, BIO proposes utilization of a simple statement of the utility requirement that is grounded on the concept of the invention having a specifically defined practical application that is appreciated by the inventor/applicant at the time the applications was filed, and is independent of whether a “technical effect” is present” or whether an application of the invention in some “industry” is defined. One formulation for treaty language that would establish this standard is:

An invention shall be deemed to be industrially applicable if, at the time of the filing of the patent application, a practical and specifically defined use for the invention in any field or in any industry is identified by the applicant

Under this standard, an applicant would be required to identify a practical utility for each claimed invention. The standard tracks the U.S. requirements that utility be specific to the invention claimed, and that this utility be “practical” – the term “practical” application would encompass the requirements that the utility be credible and substantial (e.g., not be an abstract idea or a law of nature or be inoperable). Such a formulation avoids imposing a requirement that the invention be required to have a defined application in a field of industry or have a technical character.

C. Disclosure Requirements

Question from PTO

(3) United States law currently provides for an enablement requirement, a written description requirement and a best mode requirement for patent disclosures. As to enablement, the standard of “undue experimentation” is applied. Regarding written description, United States law requires that the description convey to one of ordinary skill in the art that the applicant had possession of the invention as of the filing date of the application. The best mode requirement under United States law contains both subjective and objective components, with a subjective inquiry related to concealment on the part of the applicant. Standards vary among different patent systems as to disclosure requirements. For example, most other developed countries do not include a best mode requirement, yet many developing countries include or support a best mode requirement that is portrayed by some as a mechanism to compel technology and know-how transfer. The standard for evaluating compliance with such a requirement is an objective one; but, it is objective from the perspective of the examining authority.

BIO Position:

BIO supports a disclosure requirement consistent with the U.S. requirements of enablement and written description. BIO opposes inclusion in the treaty an obligation to disclose the best mode, framed either as a subjective (i.e., U.S. style) or objective obligation.

BIO strongly opposes inclusion in the disclosure requirement provisions of the treaty any obligation to identify the genetic origin of living material used in making the invention. Likewise, BIO opposes the inclusion as a disclosure requirement information demonstrating compliance with national laws governing access to or use of genetic resources or information held by individuals or “local communities.”

Remarks

The development of U.S. law and practice governing adequacy of disclosure has been influenced significantly by the field of biotechnology. In particular, through numerous examples in the biotechnology field, the U.S. standards for enablement and

written description have been developed through case law into refined and workable standards.

With respect to enablement, BIO can support either the new treaty or old treaty formulation, provided certain clarifications are made. Specifically, under either formulation, the requirement for enablement could be improved by a reference in the regulations to incorporate the factors for enablement considerations involving “undue experimentation” articulated in the case of *In re Wands*.⁴ Expressly incorporating the Wands factors into the regulations under the treaty would help ensure that the standards under the Treaty would reflect modern U.S. concepts of enablement in the field of biotechnology.

With respect to reflecting the U.S. written description requirement, BIO prefers the use of the new treaty formulation in Article 6(5) as a starting point for international harmonization on this point. This formulation appears to better reflect the U.S. concept of written description. However, this provision may require additional clarification to fully capture the recently clarified concept of written description under U.S. law (e.g., that the written description demonstrate possession of the claimed subject matter).⁵ As such, an amendment to this provision would be desirable to ensure it does reflect current U.S. practice. A suitable amendment could take the following form:

(5) [Scope of claim not to exceed scope of disclosure] The scope of the claim shall not exceed the scope of subject matter described and ~~the information~~ enabled in the application. However, the claim shall not be limited to what is expressly disclosed in the application.

Proposed Rules

X.1 [Description] A claimed invention shall be described pursuant to Article 5 where it has been set forth in the specification in a manner establishing that the applicant had completed a conception sufficient to demonstrate possession of the subject matter claimed.

X.2. A claimed invention shall be enabled within the meaning of Article 5 where it has been set forth in the specification in a manner permitting persons with ordinary skill in art to make and use the subject matter without engaging in undue experimentation.

Changing the words “information” to “subject matter” creates a form more suitable to the concept of “possession” (i.e., evidence of possession of the “thing” or “subject matter” as opposed to the volume or character of information). BIO would also support further guidance in applying this standard in the practice guidelines.

⁴ Factors to be considered in an “undue experimentation” analysis include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400,1404 (Fed. Cir. 1988).

⁵ See, e.g., *Regents of the University of California v. Eli Lilly and Company*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). See also, *Lockwood v. Amer. Airlines Co.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997) (“One shows that one is “in possession” of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. . . . One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.”)

BIO supports a prohibition against any further disclosure requirements in the treaty. Specifically, BIO opposes treaty provisions that would allow the United States to retain its “subjective” best mode requirement. Similarly, BIO strongly opposes a measure that would permit treaty signatories to require disclosure of the “best mode” measured in an objective sense (i.e., a positive obligation to determine which of multiple modes of practicing the invention is “best”). An objective best mode requirement would impose undue burdens on the patent applicant, and would give rise to groundless challenges to patents, particularly in regimes hostile to strong patent protection.

As to the format of the treaty provisions relating to disclosure, BIO also suggests a more objectively framed definition be used in place of the phrase “going beyond”. The “going beyond” phrase may not translate well into all languages, and more importantly, suggests that only those amendments *adding* subject matter would be prohibited. Amendments that delete subject matter in the original disclosure have the capacity to materially alter the nature of the disclosure of the invention, and can raise new matter issues as well. As such, BIO recommends use of a different formulation than “going beyond” to refer to “new matter” issues. Specifically, BIO recommends that a formulation capturing the concept of the “new matter” definition under U.S. law would be a better approach than that reflected in the proposed treaty language.

Having said this, BIO also recommends that the treaty language and rules provide a clear definition of what constitutes “new matter” given the lack of uniformity in global patent practice on this point. For example, Argentina applies a very strict standard with regard to claim amendments that operates to preclude the addition of claims that have literal textual support in the specification. It would thus be desirable to clarify in the treaty language and the rules the meaning of “new matter” to remove confusion on this point.

Finally, BIO strongly opposes the incorporation into the disclosure requirement of obligations that are not related to the concepts of enablement and written description. In particular, BIO strongly opposes incorporation of a requirement that patent applicants disclose:

- the geographical origin of material used to make or practice an invention, other than to the degree needed to enable practice of the invention;
- whether material or information used by the inventor to develop the invention has been obtained with consent from a source of such information (e.g., with consent from an indigenous population or local community); or
- proof of compliance with laws and regulations governing collection of samples of genetic resources (e.g., plants, microorganisms, genetic material, etc.).

We are aware of numerous recent attempts to impose obligations of this nature as a condition of patent validity, which unfairly and improperly conditions the availability and enforcement of patent rights. Such requirements are inappropriate to incorporate into

substantive patent law standards, which must be based on objectively determined compliance with well-established disclosure concepts. Placing this type of requirement into the disclosure requirement will subject patents in the biotechnology sector to groundless attacks that cannot be objectively evaluated. Moreover, BIO does not believe the patent law to be an appropriate means of enforcing compliance with genetic resource collection laws and procedures. As such, BIO would strongly oppose any treaty that includes as a disclosure requirement an obligation to provide information not necessary to support enablement and written description of the claimed subject matter.

D. Claim Content and Form

Question from PTO

(4) As to the contents of claims, some patent systems require the identification of "technical fields" to which the claimed invention relates. This apparently limits, to some degree, the categories of invention to which claims may be directed. There is no such requirement under current United States law.

BIO Position:

BIO supports the new style or old style treaty formulation of claim form requirements only to the extent that they are modified to conform to the minimal U.S. requirements applicable to claiming. In particular, BIO opposes requirements for:

- "conciseness" in claiming;
- recitation of the "technical field" of the invention in the claim; and
- so-called "two part" style ("Jepson style") claims, where the "prior art" must be recited in the claim;

BIO's position applies to requirements imposed by treaty articles, rules and practice guidelines promulgated under the treaty.

BIO strongly opposes any claim form requirement that would limit patent-eligible subject matter through claiming or claim form provisions or rules. Instead, BIO supports rules that would require that the applicant to present claims in such a manner as to identify only those functional and/or physical attributes of the invention that are necessary to adequately define the invention.

Remarks

The United States system provides the greatest degree of freedom in formulating and presenting claims. This freedom has enabled the precise definition of inventions at an early stage of development, and avoided problems created by formalistic hurdles in

Europe (e.g., “second medical use” claims). As a consequence, U.S. law is preferable to practices in other jurisdictions as to the how claims are formulated, and should serve as the basis for claim format in the treaty.

Having said this, the proposed treaty provisions, either in new or old style format, are essentially unobjectionable to BIO as they can be interpreted in a manner consonant with U.S. patent law, noting the earlier presented observations on written description. The rules accompanying the two treaty options, however, should be amended to better conform those standards to U.S. practice. Moreover, rules that purport to present “options” for claim format should be framed to remove any possible interpretation that countries may require claim format consistent with only one of the options presented, particularly proposed Rule 3(3) concerning “Jepson”-style claims.

BIO also believes that proposed Rule 3(2) must be amended to remove any obligation to define the invention in the claims in terms of the “technical” features of the invention. It is not clear whether this permits a practice of defining subject matter in a claim using a combination of structural and functional terms or a restatement of a requirement for the invention to have a “technical effect.” To remove the confusion, either the rule should be amended to better define the obligation or a clarification should be inserted into the practice guidelines to illustrate how terms in claims may be employed to define the invention. A possible formulation of the rule to permit any combination of structural and functional characteristics of the invention is shown below:

(2) [Method of Definition of Invention] The definition of the matter for which protection is sought shall be set forth in terms that identify the relevant features of the subject matter claimed, including through recitation of physical or functional features or attributes of the invention.

E. Unity of invention

Question from PTO

(5) With regard to the issue of multiple inventions contained in a single patent application, most of the world uses a “unity of invention” standard, which is also contained in the Patent Cooperation Treaty (PCT). For national applications, the United States currently uses a restriction practice based on independence and patentable distinctness between claimed inventions.

BIO Position:

BIO supports a treaty that mandates U.S. adherence to a unity of invention standard. BIO also recommends that the PTO unilaterally implement a unity of invention practice to replace existing restriction practices.

Remarks

The United States has been under an obligation to follow the proposed unity of invention standard since it adhered to the Patent Cooperation Treaty. The PTO, however, has not implemented a PCT and EPC-style unity of invention practice with respect to U.S.-national applications, either in terms of defining what subject matter constitutes a single inventive concept or how additional inventions can be examined within a first application through payment of an additional fee.

To implement the proposed standard, the PTO will have to make significant changes as to how it presently handles prosecution of families of applications. First, the PTO does not follow PCT-style practices when additional inventions are identified beyond the first group. Thus, instead of paying an additional fee to provide for examination of an additional invention, applicants must file additional applications, which may or may not go to the same examiner, and which often add several months of delays to the examination of the additional inventions. Second, the PTO will need to change how it handles examination of cases involving distinct inventions that are to be examined concurrently in a single examination, particularly where the original examiner does not have the expertise for the additionally elected inventions. Finally, the PTO needs to ensure that examiners are not prejudiced in terms of their ratings for productivity by the changeover to the unity of invention model. In this last area, we note that if examiners believe that the unity of invention model makes it more difficult for them to achieve their productivity ratings, it will be difficult to implement any change. It is for these reasons that BIO believes the PTO should develop and implement a plan for changing U.S. practice to follow the unity of invention model in the United States immediately, rather than await conclusion of a prospective harmonization treaty.

F. Prior Art Effect of Patents Claiming Benefit of Foreign PriorityQuestion from PTO

(7) Current discussions in the SCP have indicated a willingness to implement a global priority date as to the prior art effective date of patent applications that are published or granted as patents. United States law now limits the prior art effective date of United States patents and United States patent applications to their effective filing date in the United States. See In re Hilmer, 359 F.2d 859 (CCPA 1966) and 35 U.S.C. 102(e). Further, United States law currently limits the prior art date as to foreign patent publications to their publication date, although international application publications are available as of their filing date, if published in English. See 35 U.S.C. 102(e).

BIO Position:

BIO supports reform of the U.S. law to provide a prior art effect for the whole contents of U.S. published applications and U.S. patents as from the priority date (including where the application or patent makes a

claim pursuant to the Paris Convention) as an essential prerequisite to implementation of a “first-inventor-to-file” system in the United States.

Remarks

The United States differs from most of the world in respect of its practices concerning the prior art effect of patents and published applications that claim the benefit of an earlier filed foreign application. In the United States, acts that occur between the foreign and U.S. filing dates cannot deprive the patent applicant of obtaining the U.S. patent. However, for prior art purposes, the foreign filing date will not be treated the same as a U.S. application filing date. Specifically, under the rule established in *In re Hilmer*⁶, the prior art effective date for a U.S. patent will be the actual U.S. filing date, not the constructive filing date afforded through a foreign priority claim. In contrast, in Europe and in Japan, the foreign priority date will be recognized for both priority and for prior art purposes, although for the latter, the effect will be for novelty purposes only during the period prior to publication of the application.

Certain countries have made overruling the *Hilmer* doctrine a priority for the harmonization negotiations, whether or not the United States moves to a “first-inventor-to-file” rule. In view of this fact, and more importantly as a practical matter, it will be necessary to harmonize the “rule” governing the prior art effect of a foreign priority filing. In a “first-to-file” system, the Paris Convention must be interpreted to force the recognition of a foreign priority date – at least for novelty-defeating purposes – in order for the priority right to have meaning. Indeed, without a uniform standard, there could be different results as to the granting of patents among different jurisdictions (e.g., a patent will not issue on a later filed application in a country that confers a prior art effect as of foreign priority date, while it could issue in the country that does not confer prior art effect as of such date). Since the United States is the only country that follows the *Hilmer* rule, it would seem to be a difficult task to retain this standard if we preserve a “first-to-invent” system and categorically impossible in a “first-inventor-to-file” system.

The formulation of proposed Article 9(2) in the “old style” treaty would explicitly foreclose the possibility of the United States retaining the *Hilmer* doctrine. In both the old style and the new style treaties, however, there is a second option of silence on the effective date for prior art purposes of patents that include a foreign priority claim. Given the importance of creating a harmonized standard on prior art, this does not appear to be a feasible or even desirable option.

The remaining question thus is whether BIO should encourage the United States to change its practice unilaterally or retain this element as a negotiating variable. Given the globally focused patent procurement strategies that most biotechnology companies follow, there seems to be little objective benefit to suggesting that the United States fight to retain the *Hilmer* doctrine. In light of this and the above remarks, BIO should support a provision comparable to that found in Article 9(2) of the old style treaty.

⁶ 359 F.2d 859 (CCPA 1966).

G. Secret Prior Art

Question from PTO

(8) United States practice allows patent applications to be considered prior art as to situations of both novelty and obviousness, provided the application is earlier filed and is published or granted as required by 35 U.S.C. 102(e). Some other patent systems apply this type of prior art only with respect to novelty, due to concerns of the effect of what may be considered "secret" prior art. Such a novelty only system, however, may also allow for the granting of multiple patents directed to obvious variations of inventions.

BIO Position:

BIO supports a treaty provision that will confer a prior art effect for patents and published patent applications as from the effective filing date of the application for purposes of determinations of both novelty and nonobviousness.

BIO also opposes any treaty that does not preclude the possibility of "self collision" of applications that would become prior art under only this standard but in which there is a common basis for ownership (e.g., where the applications are commonly owned or subject to a joint interest).

Remarks

The prior art status of earlier filed applications with respect to a pending application is an area that is in need of harmonization.⁷ For example, the United States will confer a full patent-defeating effect (i.e., for both novelty and non-obviousness purposes) as from the filing date of the U.S. application.⁸ In contrast, European and Japanese practices only confer a "novelty defeating" effect for the application while it is "secret" prior art (i.e., after filing but before publication of the application). As was the case in respect of the prior art effect of patents and published patent applications that include a foreign priority claim, there needs to be harmonization of this standard in order to provide a uniform patentability standard.

⁷ The term "secret prior art" means prior art that is not publicly available prior to the filing of an application but which is applied to the application due to the presence of the information in an earlier filed application. This practice in the United States is governed primarily by 35 U.S.C. 102(e).

⁸ The United States also varies the application date of the secret prior art depending on the type of application in question. U.S. patents maturing from an international application designating the United States gain their prior art effective date under 35 U.S.C. 102(e) as from the date of compliance with the requirements of 35 U.S.C. 371. Patents including a foreign priority claim enjoy a 102(e) date only from the date of filing of the U.S. application. Patent applications have a 102(e) date that varies depending on whether there is a foreign priority claim and whether the application is an international application, and, depending on pending legislation, when the application was filed and published.

Secret prior art has more significance in systems that follow the first-to-file rule. In the United States, an applicant in most instances can avoid the patent defeating effect of secret prior art by demonstrating a date of invention prior to the filing date of the application giving rise to the secret prior art. While this may give rise to a conflict over priority of invention that has to be resolved through an interference proceeding, it does obviate the patent-defeating effect of the earlier filed application under 102(e). In systems following the first-to-file rule, “swearing behind” the secret prior art bar date is not possible, as the earlier filed application by statute will win the inventorship priority contest.

A satisfactory and workable “secret prior art” standard is a crucially important in an exercise that will harmonize priority of invention to follow the first-to-file standard. Two issues are of particular importance in this regard.

- First, the practices of the United States are in the minority with respect to the scope of the patent-defeating effect of the secret prior art. In most countries, the secret prior art will have a patent-defeating effect only for purposes of novelty determinations. In the absence of protections through a first-to-invent system, the novelty-only standard could theoretically preserve some capacity for later filed inventors to receive some scope of protection, but on merely “obvious variants” of the first-filer’s invention. While this would preserve some scope of protection for the later-filing applicant, it could create situations where two patent owners, both with valid patents, could attempt to extract royalties from a third party, and would thus weaken the first-to-file rule. BIO thus supports a rule of conferring a complete patent-defeating effect for secret prior art (i.e., for both novelty and nonobviousness purposes).
- Second, secret prior art in systems that rely on an “absolute” novelty standard can give rise to a practice of “self-collision” (i.e., where the application giving rise to secret prior art is owned by the same applicant). This is an extremely undesirable aspect of the EPC system that is only partially addressed by the provision of a grace period (i.e., one year of the secret prior art, rather than the full 18 months). BIO thus believes it is essential that the treaty provide for no possibility of “self-collision” of applications in which there is a joint or common ownership (e.g., where both applications are owned by the same entity) during the period of time where secret prior art would otherwise cause such collision. Protection against self-collision should not be extended to unrelated filings that occur after publication of the first application.

I. Grace period

Question from PTO

(9) United States patent law provides a “grace period”. Disclosures by the inventor during the “grace period” do not have a patent defeating effect. Some other systems have an “absolute novelty” requirement such that any

disclosures, including those by an inventor himself, made prior to the date the application is filed, are considered prior art.

BIO Position:

BIO strongly supports inclusion of a grace period for prior art determinations that is personal to the patent applicant (i.e., applies to disclosures arising from the applicant).

Remarks

The inclusion of a grace period in a patent law harmonization treaty is a prerequisite for BIO support for treaty implementation in the United States. The significant question that remains to be determined is the form of the grace period. In this respect, two options exist:

- A personal grace period that requires proof that the disclosure that would otherwise constitute a patent-defeating disclosure had its origin with the applicant. Thus, a voluntary communication to the public by the patent applicant would be excused, as would an unauthorized disclosure (e.g., by a third party who has derived the information from the patent applicant).
- An absolute grace period that requires no proof of linkage between the information disclosed and the patent applicant. This standard would excuse any disclosures, including by third parties, that occur during the one year period of the grace period.

The “old style” treaty would create a personal grace period, while the “new style” treaty would create an absolute grace period.

BIO supports a formulation for the grace period that would link the grace period to disclosures emanating from the applicant for the patent, rather than a formulation that would provide for an “absolute” grace period. A grace period linked to information emanating from the inventor or the applicant is more consistent with the first-to-file standard, and is a reasonable standard that will protect the inventor from what are in essence his own disclosures. In principle, BIO supports the formulation of the grace period provided in the “old-style” treaty, which addresses voluntary and unauthorized disclosures, provided that the formulation be defined to encompass disclosures that emanate from individual inventors that make up the inventive entity, as well as from the applicant.

J. Territorial limitations on patent-defeating disclosures

Question from PTO

(10) Recent discussions at the SCP have indicated a willingness on the part of many member states to eliminate any geographical restrictions that limit the definition of prior art. Currently, United States prior art requirements

limit certain types of disclosures to acts within particular geographical limitations, such as the territory of the United States.

BIO Position:

BIO supports in principle the definition of prior art as forwarded in either form of the treaty, provided that clarifications are made as to the form and characteristics of the information constituting the prior art disclosure. The clarifications in the treaty should define the attributes of the information that confer on it status as prior art (e.g., public availability in the sense of being reasonably and effectively accessible to persons of ordinary skill in the art).

Remarks

The United States currently limits the scope of patent-defeating disclosures in a number of important respects. First, patents and printed publications confer an unrestricted prior art effect for novelty and non-obviousness purposes pursuant to 35 U.S.C. 102(a) and (b). Second, information not in the form of a patent or printed publication can have a patent defeating effect if it is publicly known in the United States (i.e., not outside the territories of the United States). Third, patents confer a patent-defeating effect during the period of their pendency as applications that

Both versions of the treaty adopt the same basic concept of defining prior art to include information available to the public anywhere in the world. Either version of the treaty would thus change U.S. law as to information not in the form of patents or printed publications.

Many developing countries have supported efforts to give status to informally published or disseminated “knowledge” shared within local communities within their territory. In addition, in light of internet-based dissemination of information, questions as to whether information disseminated electronically constitutes a “printed publication” have arisen. For this reason, BIO recommends that the treaty articulate a functional definition of prior art to elucidate the conditions that would justify use of information that is publicly disseminated, to ensure that a clear and consistently applied definition of a patent-defeating disclosures is established.

An appropriate functional definition of prior art should be included in the treaty, along with clarifications to the different types of prior art in the rules and practice guidelines. It is particularly important that a workable definition be established for information to qualify as prior art, and that this definition draw on standards evolved through U.S. practice. For example, in In re Hall, the court considered the attributes of a doctrinal thesis relevant to its role as prior art. The issue was whether the thesis was available as a “printed publication” more than one year prior to the application's effective filing date of February 27, 1979.⁹ The Federal Circuit concluded that competent evidence of general library practice may be relied upon to establish an approximate time when a

⁹ 228 U.S.P.Q. 453 (Fed. Cir. 1986).

thesis became accessible. Affidavits from the director and manager of the library were relied upon by the PTO. The librarian testified that the dissertations were received in the library in November of 1977 and by December 1977 had been indexed in a special dissertations catalogue which was part of the general users' catalogue and were available to the public.

The court discussed the "printed publication" bar of Section 102(b) and stated that this bar is grounded on the principle that once an invention is in the public domain, it is no longer patentable by anyone. Because there are many ways in which a reference may be disseminated to the interested public, "public accessibility" has been called the touchstone in determining whether a reference constitutes a "printed publication" bar under 35 U.S.C. §102(b). The Section 102(b) publication bar is a legal determination based on underlying fact issues, and therefore, must be approached on a case-by-case basis. The proponent of the publication bar must show that prior to the critical date, *the reference was sufficiently accessible, at least to the public interested in the art, so that one examining the reference could make the claimed invention without further research or experimentation.*

The present treaty formulation and rules do not provide sufficient structure for determining what information will qualify as "prior art." In this respect, several changes should be made to both the treaty language and the rules to establish the characteristics of information that will confer a patent defeating effect. In particular, to qualify as prior art under the treaty, the information should be required to be supported by evidence that establishes the date, scope and contents of the public disclosure and that the information was reasonably and effectively accessible to persons skilled in the art to which the claimed subject matter pertains.

K. Loss of Right Provisions

Question from PTO

(11) United States law provides for loss of right provisions, as contained in 35 U.S.C. 102(c) and 102(d), that discourage delays in filing in the United States. Further, 35 U.S.C. 102(b) bars the grant of a patent when the invention was "in public use or on sale" more than one year prior to filing in the United States. Secret commercial use by the inventor is covered by the bar in order to prevent the preservation of patent rights when there has been successful commercial exploitation of an invention by its inventor beyond one year before filing. Most other patent systems do not have such provisions.

BIO Position:

BIO supports the current treaty structure that reduces the number of "loss of right" conditions as compared to U.S. law and practice.

Remarks

The proposed treaty would establish a patent system that is based on the first-to-file concept and extends the effect of prior art beyond national boundaries. In light of these two significant changes, many of the “loss of right” provisions in U.S. law either would not longer be relevant or would not be necessary to protect the public interest served by the relevant loss of right provision.

In particular, under the proposed treaty in either formulation, there would be no possibility of losing the right to a patent due solely to the (i) abandonment of the invention or (ii) public use or sale of the invention. Instead, under the liberalized prior art definition, public disclosures, including in the form of proof of public knowledge of the invention, would operate to preclude the patentability of the invention. There would be no sanction for abandonment of the invention, presumably because under a first-to-file system, there is sufficient motivation for early filing of patent applications after an invention has been made.

The approach embodied in either form of the draft treaty is compatible with the goals of BIO of achieving harmonization.

L. Use of Explanatory References in Novelty RejectionsQuestion from PTO

(12) Current United States novelty practice allows, in limited [[Page 15411]] circumstances, the use of multiple references for the anticipation of a claim under 35 U.S.C. 102. These circumstances include incorporation by reference, the explanation of the meaning of a term used in the primary reference or a showing that a characteristic not disclosed in the primary reference is inherent. Some other systems have stricter requirements for the use of additional references as to the determination of novelty.

BIO Position:

BIO supports a formulation of the definition of novelty that provides that an invention will lack novelty if each element of the invention is disclosed in a single item of prior art, provided, however, that in establishing the meaning and scope of the single item of prior art, resort may be had to extrinsic evidence.

Remarks

The proposals being advanced in the new and old-style treaty formulations concerning novelty attempt to foreclose the practice of use of multiple references to demonstrate that an invention lacks novelty. While BIO supports the principle of this concept (i.e., that references disclosing discrete elements of an invention may not be combined to show that the invention lacks novelty), it is concerned that the current

formulations seem to foreclose use of additional prior art disclosures to interpret the meaning of the prior art item against which novelty is being measured.

Adopting an overly formalistic novelty standard would require changes to existing U.S. practice. Under such practice, extrinsic evidence (e.g., additional references) can be considered and used by the PTO to demonstrate and clarify the content of a disclosure that is being cited for a novelty determination. Certainly, the additional information in the additional references may not be “combined” in a manner similar to formulation of a *prima facie* obviousness determination. However, use of additional references is and should continue to be permissible to demonstrate the “inherent” characteristics of subject matter disclosed in the patent or printed publication. Given the need to resort to such extrinsic evidence to demonstrate what is disclosed in a prior art patent or printed publication in the biotechnology industry, some flexibility should be reserved under the treaty for this purpose.

Accordingly, BIO supports a formulation to replace the old and new style formats that (a) specifies that novelty will be lacking if each element of the invention is fully disclosed in a single item of prior art, and (b) permits consideration of extrinsic evidence to ascertain the scope and content of the single prior art disclosure.

M. *Graham v. Deere* or Problem-Solution Analysis for Inventive Step

Question from PTO

(13) United States practice in determining obviousness under 35 U.S.C. 103 follows the practice set forth in Graham v. John Deere, 383 US 1 (1966), and its progeny. Obviousness determinations vary throughout different patent systems. For example, some provide for a problem-solution approach, requiring the identification of a technical problem to be solved by the invention. There is no such requirement under United States law.

BIO Position:

BIO supports use of the U.S. style non-obviousness determination, as opposed to a “problem-solution” approach employed in the EPO and JPO. BIO also supports a clarification in the treaty and in the practice guides that ensure that compliance with an objectively framed non-obviousness requirement entitles the patent applicant to the grant of the patent.

Remarks

The conclusion that an invention does or does not possess an inventive step or is nonobvious frequently is reached through very different paths in the EPO, JPO and the USPTO. Harmonization of the procedures by which nonobviousness determinations are made would thus be helpful to BIO members in their efforts to obtain patent rights.

Given the complexity of this issue, however, the best that may be possible is to define the non-obviousness requirement in primarily objective terms in the treaty and regulations, and to clarify the methodology for making these determinations through the practice guidelines.

As to substance, BIO should support the use of a U.S. style approach in applying the requirement for non-obviousness. In particular, the treaty should provide the patent applicant with the right to demonstrate that an invention has an inventive step or is nonobvious through reliance on secondary factors. Thus, under the *Graham v. John Deere* approach, evidence should be citeable by a patent applicant to overcome a prima facie finding of obviousness. While much of this may be achievable through practice guidelines, it would appear necessary to present this in the treaty text and/or regulations to ensure secondary factors be accorded significance under the treaty structure.

With this in mind, BIO believes that amendments should be made to the treaty text and/or the draft rules to incorporate more of the U.S. aspects of its nonobviousness standard.

N. Multiple Dependent Claim Practice

Question from PTO

(14) Current United States practice limits the filing of multiple dependent claims in 37 CFR 1.75(c) such that these claims must refer to the claims from which they depend only in the alternative. Further, a multiple dependent claim cannot depend from another multiple dependent claim. Some other patent offices allow for multiple dependent claims without these restrictions.

BIO Position:

BIO supports a liberalized practice on multiple dependent claiming and, as such, believes that U.S. practice should be adapted to practices followed in the EPO, JPO and other offices.

Remarks

No cogent reasons appear to exist that should prevent the United States from adhering to the more liberal international norms for claiming. The existing U.S. restrictions on multiple dependency add unnecessary cost and complications to the task of claim drafting. Provided a claim clearly defines the subject matter for which protection is sought, freedom in presentation and form of such claims should be permitted. Consequently, BIO supports a multiple-claim practice consistent with that followed in the EPO, Japan and other countries.

O. Claim Construction

Question from PTO

(15) There has also been discussion within the SCP regarding the manner in which claims should be interpreted as to validity. It is not clear at this time whether both pre-grant and post-grant interpretation issues will be addressed. However, we are interested in comments with regard to any claim interpretation issues at this time as these issues may appear in future SCP meetings. For example, the United States generally subscribes to a peripheral claiming approach to interpretation in which the language of the claims dominates, although United States law provides that when an element in a claim is expressed as a means or step for performing a function, the claim will be construed to cover the corresponding structure, material or acts described in the specification and equivalents thereof, see 35 U.S.C. 112, paragraph 6. Other systems take a different, centrally focused view of the claimed invention that allows, in certain circumstances, for broader interpretation of the scope of the claimed invention.

BIO Position:

BIO reserves comment until such time as this issue appears ripe for discussion within the WIPO process.

Remarks

The current exercise in WIPO has been limited to discussion of certain issues related to the procurement of patents. It has not been focused on interpretation of rights, or enforcement issues. The question of claim interpretation is therefore not ripe for discussion within WIPO, but is one in which BIO members have a significant interest. Consequently, if the topic is pursued, BIO will prepare supplemental observations to convey its views.

P. Doctrine of Equivalents

Question from PTO

(16) With further regard to claim interpretation, the United States currently applies the "doctrine of equivalents" when appropriate in interpreting claims in post-grant infringement cases. The "doctrine of equivalents" has continued to evolve in the United States, especially in view of the recently decided case of Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000). Furthermore, the European Patent Convention (EPC) was recently amended to provide a more explicit basis for "doctrine of equivalents" determinations in the text of newly added Article 2 of the Protocol on the Interpretation of Article 69 EPC. This doctrine has also been recognized in litigation in Japan. However, some systems do not provide for such equivalents.

BIO Position:

BIO reserves comment until such time as this issue appears ripe for discussion within the WIPO process

Remarks:

This is an “enforcement” issue, not technically germane to substantive patentability. On this basis, BIO would reserve comment on this issue at this time. However, BIO strongly believes that “claim construction” issues should be addressed, both in the context of claims under examination and claims in issued patents, inherently implicating the “doctrine of equivalents” as a subject to be addressed in a patent harmonization treaty, even one limited to substantive patentability requirements.

Q. Filing by Assignees

Question from PTO

(17) United States practice now requires that a patent be applied for in the name or names of the inventor or inventors. However, some systems allow for direct filing by assignees. Although the draft treaty text is currently silent on this issue, it may be raised at future meetings.

BIO Position:

BIO supports conferring on assignees the right to file patent applications owned by those entities.

Remarks

The issue of assignee filing is not addressed in the treaty in its present form. Assignee filing would facilitate the filing of patent applications by obviating the need for each application to comply with formalities of inventor signatures and the like in filing applications. Given that this measure would simplify the process of filing applications already owned by the assignee, it should be supported by BIO.

III. Concluding Remarks

The goal of substantive harmonization is worthy of a significant effort and commitment from the United States Government. A truly harmonized set of standards for patent law will materially improve the ability of our industry to gain the benefit of their innovations. As noted above, we believe substantive harmonization of patent law standards must be pursued in conjunction with creation of a facilitated patent granting system through the PCT. We look forward to working with you as you commence this process.

Sincerely,

A handwritten signature in black ink, appearing to read "Carl Feldbaum", followed by a long horizontal line extending to the right.

Carl Feldbaum
President